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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Diclazuril

AGENCY: Food and Drug Administration, HI-IS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations for medicated feed applications to add an entry stating the maximum Type B level and assay limits for diclazuril Type B and C medicated feeds. The **Federal Register** document that reflected approval of Schering-Plough Animal Health Corp.'s new animal drug application (NADA) for use of diclazuril Type A medicated articles for making Type C medicated broiler feeds failed to provide that entry.

DATES: This regulation is effective *[insert date of publication in the* **Federal Register].**

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 2, 1999 (64 FR 35923), FDA published a final rule that reflected the approval of Schering-Plough Animal Health Corp.'s NADA 141-951. The NADA provides for use of a Type A medicated article containing 0.2 percent of diclazuril (CLINACOX™) to make Type C broiler feeds used for the prevention of coccidiosis. The final rule added 21 CFR 556.175 and 558.198 to reflect the approval, but failed to amend § 558.4 (21 CFR 558.4) to add an entry stating the maximum Type B level and assay limits for

diclazuril Type B and C medicated feeds. At this time, § 558.4 is amended in paragraph (d) in the table "Category I" accordingly.

As provided in 2 1 CFR part 20 and 5 14.11 (e)(2)(ii), a freedom of information summary of safety and effectiveness data and information required to support approval of the application was placed on file in the Dockets Management Branch, Food and Drug Administration, upon publication of the approval.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of ' 'particular applicability. '' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.4 is amended by adding an entry alphabetically to Category I the table in paragraph (d) to read as follows: PU Ruth P.

§ 558.4 Requirement of a medicated feed mill license.

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(d) * * *

CATEGORY I

Drug	Assay limits percent [1] type A	Type B maximum (200x)	Assay limits percent [1] type B/C*
Diclazuril	90-110	182 g/t (0.02%)	85-I 15/70–120

[1] Percent of labeled amount.
[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drug that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

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Dated: 12/14/99
December 14, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Claire M. Lathers

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